OCT 3 1 2005

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Prepared March 28, 2005

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Kyung-Am, Shim
Regulatory Affairs Manager
Medison Co. Ltd.
997-10, Daechi-dong, Gangnam-gu,
Seoul 135-280, Korea
Telephone: 82.2.2194.1381
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Email: kashim@medison.com

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

ACCUVIX XQ ™ Diagnostic Ultrasound System and Transducers

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. Identification of the predicate or legally marketed device:

Medison Co., Ltd. believes that ACCUVIX XQ ™ ultrasound system is substantially equivalent to the currently marketed SONOACE 9900 PLUS ultrasound system (K032329) and SONOACE 9900 ultrasound system (K012867 and K002185)

4. Device Description:

The ACCUVIX XQ ™ is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler imaging, Power Doppler imaging, Harmonic imaging, and PW Spectral Doppler mode on the CRT display. It also provides the 3D imaging mode using the 3D probe in the Mechanical scan mode.

The ACCUVIX XQ ™ has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed. The

system also provides for the measurement of anatomical structures and for analysis packages that provide information used for clinical diagnostic purposes by competent health care professionals.

The ACCUVIX XQ ™ has been designed to meet the following electromechanical safety standards:

- UL 60601-1, Underwriters Laboratories Standards, Medical Electrical Equipment
- C22.2 No. 601.1, Canadian Standards Association, Medical Electrical Equipment
- EN 60601-1, European Norm, Medical Electrical Equipment
- EN 60601-1-2, European Norm, Collateral Standard: Electromagnetic Compatibility
- IEC 61157, International Electrotechnical Commission, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment
- ISO10993, Biological evaluation of medical devices

3. Intended Uses:

The ACCUVIX XQ ™ system and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.
The clinical applications include:
Fetal (including infertility monitoring of follicle development), Abdominal, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esophageal, Muscular-skeletal, Urology, TCD, Cardiac (Adult, Pediatric), and Peripheral-vascular (Carotid, Arterial, Venous) applications.

6. Technological Characteristics:

The ACCUVIX XQ ™ is substantially equivalent to the SA-9900 PLUS Diagnostic Ultrasound System, cleared via K032329, and the SA-9900 Diagnostic Ultrasound System, cleared via K002185 and K012867. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

7. Conclusion:

The ACCUVIX XQ™ 510(k) Pre-Market Notification contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

ACCUVIX XQ™ will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Moderate"

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2005

Medison Co., Ltd.
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Serves NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052911
Trade Name: ACCUVIX XQ™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 14, 2005
Received: October 17, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ACCUVIX XQ™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3D3-5EK Curved Array
3D4-7EK Curved Linear Array
3D5-8EK Curved Linear Array
C2-61C Curved Array

C3-7IM Curved Array
C5-2EL Curved Array
CW2.0 Static CW
CW4.0 Static CW
EC4-9IS Curved Array
L5-9EE Linear Array
L5-12IM Linear Array
L6-12IS Linear Array
L8-I5IS Linear Array
MPT4-7AO Multiplane TEE
P2-4AC Phased Array
P3-5AC Phased Array
P3-7AC Phased Array
VAW3-5 Curved Array
VAW4-7 Curved Array
CDW5-8 Curved Array
VNA6-12 Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Section 4.3 INDICATIONS FOR USE

DIAGNOSTIC ULTRASOUND INDICATIONS STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N	N	N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N	N	N	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note 1	Note 2,4,5,6,7,8,9
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2,5,6,8,9
	Neonatal Cephalic	N	N	N	N	N	Note 1	
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal	N	N	N		N	Note 1	Note 2, 3, 8
	Trans-vaginal	N	N	N		N	Note 1	Note 2, 3, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N	N	N		Note 7, 8
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2,5,6,8,9
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2,5,6,8,9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note 1	Note 7, 8
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note 1	Note 5, 6, 9
	Other (spec.)				N			

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **3D3-5EK Curved Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **3D4-7EK Curved Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **3D5-8EK Curved Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	Note 1	Notes 2, 8
	Trans-vaginal	N	N	N		N	Note 1	Notes 2, 8
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix F

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **C2-6IC Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **C3-7IM Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Notes 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication: P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **C5-2EL Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	N	N	N		N	Note 1	Notes 2, 7, 8
	Abdominal	N	N	N		N	Note 1	Notes 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Notes 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **CW2.0 Static CW**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic				P			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric				P			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				P			
	Other (spec.)				P			

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **CW4.0 Static CW**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic				N			
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult				N			
	Cardiac Pediatric				N			
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel				N			
	Other (spec.)				N			

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **EC4-9IS Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 8
	Trans-urethral	P	P	P		P	Note 1	Note 2, 8
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **L5-9EE Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 8, 9
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 8, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 8, 9
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 8, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E = added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **L5-12IM Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 5, 6, 9
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 5, 6, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 5, 6, 9
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 5, 6, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note 1	Note 5, 6, 9, 10
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **L6-12IS Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 5, 6, 9
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler

Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M

Note 2: Includes imaging for guidance of biopsy

Note 3: Includes infertility monitoring of follicle development

Note 4: Color M-mode

Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients

Note 6: Abdominal organs and peripheral vessel

Note 7: Tissue Harmonic Imaging (THI)

Note 8: 3D imaging

Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal,

Mechanical Devices

K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **L8-15IS Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Small Organ *(See Note 5)*	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Musculo-skel. (Superfic.)	N	N	N		N	Note 1	Note 2, 5, 6, 9
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 5, 6, 9
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **MPT4-7AO Multiplane TEE**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	N	N	N		N	Note 1	Note 7, 8
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N		N	Note 1	Note 7, 8
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **P2-4AC Phased Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **P3-5AC Phased Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal	N	N	N	N	N	Note 1	Note 4, 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	N	N	N	N	N	Note 1	Note 4, 7, 10
	Cardiac Pediatric	N	N	N	N	N	Note 1	Note 4, 7, 10
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **P3-7AC Phased Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal	P	P	P	P	P	Note 1	Note 4, 7
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note 1	Note 4, 7
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note 1	Note 4, 7
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	Note 1	Note 4, 7, 10
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **VAW3-5 Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **VAW4-7 Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*	P	P	P		P	Note 1	Note 2, 7, 8
	Abdominal	P	P	P		P	Note 1	Note 2, 7, 8
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note 1	Note 2, 7, 8
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 7, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal
and Radiological Devices
K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **VDW5-8 Curved Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note 1	Note 2, 8
	Trans-urethral	P	P	P		P	Note 1	Note 2, 8
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal
[illegible]
K052911

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No.:
System: **ACCUVIX XQ ™ Diagnostic Ultrasound System**
Transducer: **VNA6-12 Linear Array**
Intended Use: **Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal *(See Note 3)*							
	Abdominal							
	Intra-operative *(See Note 6)*							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ *(See Note 5)*	P	P	P		P	Note 1	Note 2, 8
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Convent.)	P	P	P		P	Note 1	Note 2, 8
	Musculo-skel. (Superfic.)	P	P	P		P	Note 1	Note 2, 8
	Intra-luminal	P	P	P		P	Note 1	Note 2, 8
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N= new indication; P= previously cleared; E= added under Appendix E

Additional Comments:

Color Doppler includes Power (Amplitude) Doppler
Note 1: B/M, B/PW Doppler, B/Color Doppler, B/Color Doppler/PW Doppler, B/Power Doppler/PW Doppler, B/Color Doppler/Color M
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: Color M-mode
Note 5: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 6: Abdominal organs and peripheral vessel
Note 7: Tissue Harmonic Imaging (THI)
Note 8: 3D imaging
Note 9: Panoramic imaging

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

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